

REMARKS

I. Amendments to the Claims:

Claims 29-33, 36-42, 45, 47-50, 80-82, 90, and 92-100 are pending in this application.

Claims 34, 43, 46, 51, 53-59, 61-68, 70-78, 84-86, 91 and 101 have been withdrawn as being drawn to a non-elected invention.

Claims 102 and 103 have been newly added. Claims 29, 99, and 100 have been amended herewith. Support for the new and amended claims can be found throughout the application and claims as originally filed. Accordingly no new matter has been added.

Claim 90 has been canceled without prejudice. Applicant reserves the right to pursue the subject matter of this claim in a related application.

Upon entry of the instant amendments to the claims, claims 29-33, 36-42, 45, 47-50, 80-82, 92-100 and 102-103 will be pending in the instant application.

II. Priority:

Pursuant to 35 U.S.C. § 119(b), the Examiner requested certified copies of PP9778, PRO745, PCT/AU00/00329 and PCT/AU01/01291 priority applications. Attached as **Appendix A** are certified copies of these four priority applications.

III. Information Disclosure Statement:

Applicant thanks the Examiner for reviewing all documents submitted with Information Disclosure Statements.

IV. Rejection Under 35 U.S.C. §112, First Paragraph, Enablement:

Claims 29-33, 36-42, 45, 47-50, 80-82, and 92-100 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being non-enabling for a method of preventing any autoimmune disease in a patient. (*see*, Office Action, page 4).

The Examiner stated that the specification was enabling for a method of alleviating symptoms of an autoimmune disease in a patient. (*see*, Office Action, page 4).

Without acquiescing to this rejection, and solely with a view towards expediting prosecution of this application, Applicant has amended all pending independent claims in accordance with the Examiner's indication of enabled subject matter.

Claim 29 has been amended to recite: A method for treating or alleviating symptoms of an autoimmune disease in a patient, comprising depleting T cells in the patient; and reactivating the thymus of the patient, wherein the patient has an improved prognosis for the autoimmune disease compared to an untreated patient suffering from an autoimmune disease.

Claim 99 has been amended to recite: A method for treating or alleviating symptoms of an autoimmune disease in a patient, comprising reactivating the thymus of the patient, wherein the patient has an improved prognosis for the autoimmune disease compared to an untreated patient suffering from an autoimmune disease.

Finally, Claim 100 has been amended to recite: A method for treating or alleviating symptoms of an autoimmune disease in a patient, comprising providing the patient with immunosuppressive therapy; and reactivating the thymus of the patient, wherein the patient has an improved prognosis for the autoimmune disease compared to an untreated patient suffering from an autoimmune disease.

In view of the foregoing amendments to the claims, Applicant respectfully submits that grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

V. Rejection Under 35 U.S.C. § 102(b):

Claims 29-33, 36-42, 45, 47-50, 90, and 92-100 were rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 as evidenced by Mardiney, III *et al.* (U.S. 6,103,694). (see, Office Action, page 6).

For a reference to anticipate a claimed invention in terms of 35 U.S.C. § 102, the prior art must teach *each and every element* of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

The Office Action alleges that the teachings of Ghalie *et al.* meet every limitation of the claims. Applicant respectfully traverses this rejection for the following reason.

As a preliminary matter, Applicant notes that the claims must be considered as a whole. The independent claims as amended, and including their preambles, are directed to methods for treating or alleviating symptoms of an autoimmune disease in a patient. The treatment recited in the claims lead the patient to have an improved prognosis for the autoimmune disease compared to an untreated patient suffering from the autoimmune disease.

Ghalie is directed to the use of a synthetic analog of Gn-RH (leuprolide) to prevent heavy menstrual bleeding that occurs in pre-menopausal women undergoing bone marrow transplantation. The procedure involves a pretransplantation preparative regimen of total-body irradiation and cyclophosphamide or high-dose combination chemotherapy, administration of leuprolide at least 1 month before admission for BMT, followed by BMT. There is simply no teaching or suggestion in Ghalie of a method for treating or alleviating symptoms of an autoimmune disease in a patient, wherein the treatment leads "the patient to have an improved prognosis for the autoimmune disease compared to an untreated patient suffering from the autoimmune disease."

Because Ghalie does not teach each and every limitation of the claimed invention, Applicant submits that Ghalie does not anticipate Applicant's claimed invention. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 102(b).

VI. Rejections Under 35 U.S.C. § 103(a):

(a) Claims 29, 80, and 82 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694). (see, Office Action, page 7).

According to MPEP § 2143, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art,

to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims as amended. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, does not remedy the deficiencies of Ghalie *et al.* outlined above as it also does not teach a method for treating or alleviating symptoms of an autoimmune disease in a patient.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient. Because the combined references do not teach all claim limitations, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

(b) Claim 81 was rejected as purportedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694) and further in view of Bolotin (*Blood* 88:1887-94, 1996). (see, Office Action, page 9).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims, as amended. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, also does not remedy the deficiencies of Ghalie *et al.* outlined above.

The Office Action relies on Bolotin to teach the use of IL-7. However, Bolotin is directed to using IL-7 to promote thymic reconstitution and enhance thymopoiesis after bone marrow

transplantation (BMT) to prevent post-BMT immune deficiency. There is no teaching in Bolotin that remedies the deficiencies of the primary and secondary reference, either alone, or in combination.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient. One with ordinary skill in the art would not consider these references to be applicable in treating or alleviating autoimmune disease in patients.

Because the combined references do not teach or suggest all claim limitations, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

(c) Claim 82 was rejected as purportedly being obvious over Ghalie *et al.*, *Am. J. Hematol.*, 42:350-353, 1993 in view of Mardiney, III *et al.* (U.S. 6,103,694) and further in view of Tian (*Stem Cells* 16:193-99, 1998). (*see*, Office Action, page 10).

As discussed above with respect to the § 102 rejection above, Ghalie *et al.* do not teach or suggest all the limitations of Applicant's independent claims. The secondary reference, Mardiney, which has been used by the Office Action for teaching methods of administering certain cytokines to patients for engrafting hematopoietic pluripotent cells, also does not remedy the deficiencies of Ghalie *et al.* outlined above.

The Office Action relies on Tian to teach that growth hormone promotes hematopoietic reconstitution after syngeneic BMT and to accelerate hematopoiesis after autologous BMT. Tian does not remedy the deficiencies of the primary and secondary reference, either alone or in combination.

Applicant notes that the instant claims as amended are not directed to improving engraftment after bone marrow transplantation (BMT), but rather to a method for treating or alleviating symptoms of an autoimmune disease in a patient. Because the combined references do not teach or suggest all claim limitations, Applicant respectfully submits that the grounds for

this rejection have been overcome. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

VII. Provisional Statutory Double Patenting Rejection:

Claim 90 stands provisionally rejected under 35 U.S.C. 101 as claiming the same invention of claim 53 of U.S. Appl. 10/749,119 and claim 87 of copending Appl. 10/749,120. (*see*, Office Action, page 12).

Claim 90 has been canceled herewith. Accordingly, the grounds for this provisional rejection have been overcome. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

VIII. Provisional Obviousness-Type Double Patenting Rejections:

Claims 29-33, 36-42, 45, 47-50, 80-82, and 92-100 were provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 19-26, 28-40, 55-66, 69-72, and 74-75 of U.S. Appln. 10/749,119.

In addition, claims 29 and 99-100 were provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 26, 30, and 79 of U.S. Appln. 10/749,122, and over claim 87 of U.S. Appln. 10/749,120.

Applicant respectfully requests that the Examiner hold these provisional rejections in abeyance until such time that allowable subject matter is indicated in the instant application.

CONCLUSION

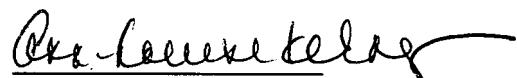
Upon entry of the instant amendments to the claims, claims 29-33, 36-42, 45, 47-50, 80-82, 92-100 and 102-103 will be pending in the instant application.

No additional fees are believed to be due in connection with this correspondence other than the fees for the Petition for Extension of Time. Please charge the payments due to our Deposit Account No. 08-0219.

If a telephonic interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: April 26, 2007



Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6192
Fax: (617) 526-5000

APPENDIX A

Attached are certifies copies of the four priority applications: PP9778, PRO745, PCT/AU00/00329 and PCT/AU01/01291.